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EXAMINER	
COUNTS, GARY W	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Attachment to Advisory Action

Continuation of 3 NOTE: Amended claim 42 requires further consideration because it raises a new 112 2nd issue, particularly; step (b) the recitation "a human subject" is vague and indefinite because it is unclear if Applicant intends the human subject recited in step (a) or if Applicant intends another human subject.

Amended claim 42 also requires further consideration and raises a new 112 first new matter rejection.

The instant amended claims would recite "and a significant deviation of any of the adjusted target quantities compared to the adjusted reference quantities is a pre-clinical or clinical indication of a specific LSD, Wherein a deviation is significant if the absolute value of the adjusted target quantity is less than 2% of the adjusted reference quantity.

Applicant argues that the amendment finds support in paragraphs 0048, 0096 and 0097. This statement is not found persuasive because after review of paragraphs 0048, 0096 and 0097 the disclosure does not provide support for the claim as amended the specification discloses that in contrast to absolute marker measurement, the multiplex allows each protein to be compared using ratios (para 0096) and teaches that MPS I multiplex ratio data for a-iduronidase to LAMP-1 was below the 2nd percentile cut-off of 16/17 plasmas and 4/4 blood spots. However, there is no description in the specification disclosing a significant deviation of any of the adjusted target quantities compared to the adjusted reference quantities is a pre-clinical or clinical indication of a specific LSD, Wherein a deviation is significant if the absolute value of the adjusted

target quantity is less than 2% of the adjusted reference quantity. Furthermore, none of the originally filed claims recited the limitations in question. Recitation of claim limitations lacking literal or adequate descriptive support in the specification or originally filed claims constitutes new matter.

Continuation of 11 NOTE: Also, the amendments filed 11/22/10 do not overcome all previous rejections for reasons stated below.

112 enablement rejections:

Applicant argues that claims 42 and 46 have been amended to recite the sample is blood or plasma. This argument is not found persuasive because amended claim 42 does not recite the sample is blood or plasma sample. Therefore the rejections would be maintained on the claims for reasons stated in the Final rejection mailed 09/27/10. Further, it is noted that the previous rejections indicated plasma and dried blood samples of human subjects and the Applicant has not amended the claims or provided evidence that any and all samples or any other sample besides plasma or dried blood is enabled. Therefore, the rejection is maintained.

112 2nd rejections:

Amended claim 42 would not overcome the previous 112 2nd rejection of claim 42 step (g) because as stated in the previous office action Claim 42, step (g) is vague and indefinite because it is unclear how the first and second fluorophores are related to detection. Also, the instant claims require the detection of multiple targets and it is unclear how one microsphere comprising only one antibody for a specific target is also

able to detect the other targets in the assay. Is there more than one type of microsphere or more than one type of antibody. How does one differentiate between the multiple targets utilizing one microsphere? Thus, it is unclear how the determination of the targets is made in the instantly recited claims. It is noted that Applicant did not specifically address the 112 2nd rejection of claim 42, step (g) or provide arguments or evidence against the rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/
Examiner, Art Unit 1641

/Melanie Yu/
Primary Examiner, Art Unit 1641